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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/722,763 | 11/28/2003 | Ada S. Cowan | 22,205 | 7216 |

26345 7590 06/29/2006

GIBBONS, DEL DEO, DOLAN, GRIFFINGER & VECCHIONE
1 RIVERFRONT PLAZA
NEWARK, NJ 07102-5497

| EXAMINER |
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ALSTRUM ACEVEDO, JAMES HENRY

| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/722,763

Applicant(s)

COWAN ET AL.

Examiner

James H. Alstrum-Acevedo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 13-29, 34-52 and 57-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 13-29, 34-52 and 57-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5/19/06; 5/22/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-7, 13-29, 34-52, and 57-68 are pending. Receipt and consideration of Applicant's arguments/remarks, amended claims, and specification, filed on April 11, 2006, is acknowledged. Applicant has cancelled claims 8-12, 30-33, and 53-56.

Specification

The objection of the specification for containing an embedded hyperlink and/or other form of browser-executable code in paragraph [0052] **is withdrawn**, per Applicant's amendments to the specification.

Upon further review of the specification, the Examiner has determined that no essential subject matter has been incorporated by reference to a foreign application or patent, or to a publication, and this objection **is withdrawn**.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claims 67 and 68 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn**, due to Applicants' amendments to said claims.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1-7, 13-29, 34-52, and 57-68 under 35 U.S.C. 102(b) as being anticipated by Thurston et al. (WO 00/66206) **is maintained**. Applicant has cancelled claims 8-12, 30-33, and 53-56.

The rejection of claims 1-7, 13-29, 34-38, 40-42, 44-52, 57-61, and 63-68 under 35 U.S.C. 102(b) as being anticipated by Fuhrman et al. (U. S. Patent No. 5,733,939) **is withdrawn**, per Applicants' amendments.

Response to Arguments

Applicant's arguments, see page 19 of Applicants' amendments/remarks, filed April 11, 2006, with respect to claims 1-7, 13-29, 34-38, 40-42, 44-52, 57-61, and 63-68 have been fully considered and are persuasive. The rejection of claims 1-7, 13-29, 34-38, 40-42, 44-52, 57-61, and 63-68 under 35 U.S.C. 102(b) as being anticipated by Fuhrman et al. (U. S. Patent No. 5,733,939) has been withdrawn.

Applicant's arguments filed April 11, 2006 with regards to the disclosure of Thurston et al. (WO 00/66206) and the rejection of claims 1-7, 13-29, 34-52, and 57-68 under 35 U.S.C. 102(b) have been fully considered but they are not persuasive. Applicant contends that Thurston only discloses ethanol and/or water as solvents and that Thurston lacks the disclosure of solvents selected from ethers and alkyl sulfoxides. The Examiner respectfully disagrees. Thurston clearly states on page 8, lines 24-26, "...the composition to be aerosolized also

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provides a carrier in which the active ingredient may be dissolved, suspended, or emulsified. A variety of solvents or emulsifying agents are suitable for this purpose...” Furthermore, the exemplified compositions (aerosol compositions 1-4) comprise a variety of cosolvents, including *polyethylene glycol*, propylene glycol, and glycerol. Polyethylene glycol is a well-known aliphatic *polyether* (see the structure below). Additionally, it is noted that pharmaceutically acceptable solvents and cosolvents are well known in the art and include alkyl sulfoxides (e.g. dimethylsulfoxide) (see, for example, McGarry: col. 3, line 60 through column 4, line 19 of U.S. Patent No. 4,618,618) Therefore, Thurston anticipates the cited claims as explained on pages 3-5 of the previous office action and Thurston does teach compositions comprising an ether.

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| <p>Ether</p> $R-O-R$ <p>R= alkyl, aryl</p> | <p>Polyethyleneglycol (a polyether)</p> $HO-(CH_2CH_2O)_n-OCH_2CH_2O-(CH_2CH_2O)_n-OH$ |
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Other Matter

It is noted that the second IDS submitted on May 22, 2006 cites the same reference cited on the IDS submitted on May 19, 2006.

Conclusion

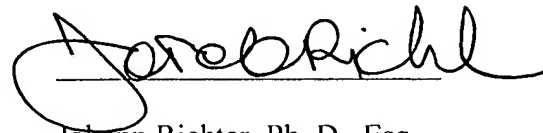
Claims 1-7, 13-29, 34-52, and 57-68 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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